

### REMARKS

Claims 46-71 are pending for examination with claims 46, 53, 59, and 65 being independent claims. Claims 65-71 have been added.

Applicants acknowledge the courtesies extended to Ms. Carole A. Boelitz and James M. Hanifin, Jr. during the telephone interview on September 17, 2003 and to Ms. Carole Boelitz during the telephone interview on October 22, 2003 (it appears that the Interview Summary mistakenly identifies the date of the interview as October 15, 2003). The substance of the discussions during the interviews are incorporated into the following remarks.

Applicants respectfully traverse each of the rejections presented in the Final Office Action of July 25, 2003 for the reasons set forth in their prior response of July 10, 2003, which is incorporated herein by reference. Applicants also submit herewith the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") to provide factual support for their positions. Mr. Eldridge has extensive experience in the soft tissue repair prosthetics industry. (See Eldridge Declaration, paragraph 2). He is familiar with the level of knowledge possessed by those of ordinary skill in the art of soft tissue repair prosthetics as of the filing date of the present application. (See Eldridge Declaration, paragraph 5). As set forth in his declaration, Mr. Eldridge disagrees with the Examiner's positions regarding the teachings of Mulhauser (U.S. patent No. 5,766,246).

#### Allowable Subject Matter

Applicants acknowledge the Examiner's indication that claims 48 and 49 would be allowable if rewritten in independent form including all of the limitations of their respective base claim and any intervening claims. These claims have not been rewritten in independent form because these depend from claims believed to be allowable as discussed below.

#### Rejections Under 35 U.S.C. § 102

Claims 46, 50, 53, 54, 56, 59, 60, and 62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mulhauser (U.S. patent No. 5,766,246). The Examiner contends that Mulhauser discloses a prosthesis and method of implanting a prosthesis that includes a polypropylene mesh

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layer, a barrier layer as shown in Fig. 3(h), and an edge barrier as shown in Fig. 3(h). Applicants respectfully traverse these rejections.

#### Claims 46 and 50

Independent claim 46 is directed to a prosthetic repair fabric for repairing a tissue or muscle wall defect. The prosthetic repair fabric comprises a layer of mesh fabric with a plurality of interstices that are constructed and arranged to allow tissue ingrowth. The mesh fabric is susceptible to the formation of adhesions with sensitive tissue and organs, and includes first and second sides and an edge extending between the first and second sides. The prosthetic repair fabric also comprises at least one barrier layer that inhibits the formation of adhesions with sensitive tissue and organs. The barrier layer is disposed on at least a portion of one of the first and second sides of the layer of mesh fabric to inhibit the formation of adhesions between the portion of the mesh fabric and adjacent sensitive tissue and organs. The prosthetic repair fabric further comprises an edge barrier that inhibits the formation of adhesions with sensitive tissue and organs. The edge barrier is adapted to isolate at least a portion of the edge of the mesh fabric from adjacent sensitive tissue and organs. Applicants respectfully submit that Mulhauser fails to anticipate claim 46.

Mulhauser is directed to an implantable prosthesis 10 having a mesh layer 12 and a semi-rigid frame 14 supporting the mesh layer. (Mulhauser, Col. 3, lines 39-49). As shown in Figs. 2 and 3(h), the frame may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge.

As discussed during the interviews, the Examiner contends that the frame 14 in Mulhauser is a barrier to adhesions with tissue and muscle, forming both an edge barrier and a surface barrier. More particularly, the Examiner maintains that the frame 14 is an adhesion resistant barrier on the basis that it may be made of a silicone material. Applicants respectfully disagree.

As discussed during the interviews, Mulhauser does not teach or suggest that the frame 14 has any type of adhesion inhibiting properties. Mulhauser only indicates that the frame 14 may be formed from an injection molded polypropylene or silicone material, or that the frame may be formed by hot or cold forming a ring-shaped depression in the mesh layer itself. (Mulhauser, Col. 4, lines 60-65). Although a silicone material may be formed into a structure

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which inhibits adhesions with tissue and muscles, silicone material does not inherently or necessarily inhibit adhesions.

As explained during the interviews, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10 $\mu$ m or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Mulhauser provides no teaching or suggestion as to any structural characteristics of a silicone frame that would determine its adhesion resistant properties. As indicated above, Mulhauser discloses only that the frame may be formed from an injection molded silicone material. However, the surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, the fact that the Mulhauser frame may be injection molded from a silicone material does not necessarily provide a frame that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

During the interviews, the Examiner also contended that that Fig. 3(h) of Mulhauser supports his position that the frame inhibits tissue ingrowth on the basis that the figure shows a smooth silicone layer. Applicants respectfully disagree. Nothing in the figure provides any indication that the frame is adhesion resistant. (See Eldridge Declaration, paragraph 11). As indicated above, the adhesion resistance of a material implanted in a body depends on the surface texture and porosity of the material and that tissue ingrowth can occur when the surface texture or porosity is approximately 10 $\mu$ m or more. (See Eldridge Declaration, paragraph 11). This amount of surface texture and porosity is microscopic and undetectable with the naked

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eye. (See Eldridge Declaration, paragraph 11). Thus, simply because the drawing in Mulhauser does not illustrate a rough surface or large pores does not indicate that the frame is resistant to tissue ingrowth or adhesions. (See Eldridge Declaration, paragraph 11).

Applicants also note that the figures of Mulhauser illustrate the frame 14 of Mulhauser using a surface symbol associated with materials having varying degrees of porosity which can be readily seen with the naked eye. For example, the Mulhauser frame is illustrated using the same surface symbol employed for various porous and relatively textured materials including, but not limited to, wood, insulation, synthetic sponge, cork, cheese and foam. See MPEP §608.02. In this regard, materials that are porous and have surface texture even to the naked eye would be illustrated without pores and surface texture following Patent Office guidelines for drawing preparation. Thus, the fact that the Mulhauser figures do not illustrate the frame as being rough or porous does not lead to the conclusion that it is smooth and resistant to the formation of adhesions. Additionally, as indicated above, the degree of surface texture or porosity of a material that would allow tissue ingrowth and adhesions is microscopic and not even visible to the naked eye. Accordingly, the Mulhauser figures do not disclose an edge barrier which inhibits the formation of adhesions with sensitive tissue and organs as recited in claim 46.

During the interviews, the Examiner further contended that the Eldridge patent (U.S. Patent No. 6,120,539) supports his position that silicone material inhibits tissue ingrowth. In particular, the Examiner alleged that the Eldridge patent discloses that silicone elastomer discourages ingrowth and serves as a suitable barrier layer. (Citing col. 3, line 60 to col. 4, line 5). Applicants respectfully disagree with the Examiner's position. A silicone elastomer is one of several disclosed materials that may be used as a suitable barrier material. However, this teaching in Eldridge does not support the Examiner's position that the Mulhauser frame is adhesion resistant. (See Eldridge Declaration, paragraph 12). As indicated above, the adhesion resistant properties of a prosthetic material is affected by the structural properties, including surface texture and porosity, of the formed material. (See Eldridge Declaration, paragraph 12). An adhesion resistant barrier layer, such as employed on the Eldridge repair fabric, requires a microporous structure having a surface texture or porosity that is less than 10 $\mu$ m. (See Eldridge Declaration, paragraph 12). This is not an inherent property of the

material itself, but varies depending upon the structure formed with the material, whether it is a silicone elastomer or other material. (See Eldridge Declaration, paragraph 12). Thus, the fact that a silicone elastomer may be employed as a barrier material does not support a conclusion that any structure formed from a silicone elastomer, such as the Mulhauser frame, is necessarily adhesion resistant. (See Eldridge Declaration, paragraph 11). Rather, an adhesion resistant barrier requires a microporous structure and structures formed from a silicone elastomer are not necessarily microporous and adhesion resistant. (See Eldridge Declaration, paragraph 12).

In view of the foregoing, claim 46 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn. Claim 50 depends from claim 46 and is patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

#### Claims 53-56

Independent claim 53 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The implantable prosthesis comprises a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs. The layer of repair fabric includes first and second sides and an edge extending between the first and second sides. The implantable prosthesis also comprises a barrier layer that inhibits the formation of adhesions with tissue and organs and is configured to inhibit the formation of adhesions between at least a portion of one of the first and second sides and adjacent tissue and organs. The implantable prosthesis further comprises an edge barrier which inhibits the formation of adhesions with tissue and organs and is adapted to cover at least a portion of the edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the edge of the layer of repair fabric and adjacent tissue and organs.

Applicants respectfully submit that Mulhauser does not anticipate claim 53. As discussed above and during the interviews, Mulhauser does not teach or suggest an edge barrier which inhibits the formation of adhesions with tissue and organs as recited in claim 53. Thus, claim 53 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn.

Claims 54-56 depend from claim 53 and are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

Claims 59, 60 and 62

Independent claim 59 is directed to a method of repairing a tissue or muscle wall defect and comprises the step of providing an implantable prosthesis. The prosthesis includes a layer of repair fabric which is susceptible to the formation of adhesions with tissue and organs. The layer of repair fabric includes first and second sides and an edge extending between the first and second sides. The prosthesis also includes a barrier layer that inhibits the formation of adhesions with tissue and organs. The barrier layer is configured to inhibit the formation of adhesions between at least a portion of the first side and adjacent tissue and organs. The implantable prosthesis further includes an edge barrier which inhibits the formation of adhesions with tissue and organs. The edge barrier covers at least a portion of the edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the edge of the layer of repair fabric and adjacent tissue and organs. The method further comprises the step of implanting the implantable prosthesis with the barrier layer and the edge barrier being positioned between the layer of repair fabric and a region of potential adhesions with tissue and organs.

Applicants respectfully submit that Mulhauser does not anticipate claim 59. As discussed above and during the interviews, Mulhauser does not teach or suggest an edge barrier which inhibits the formation of adhesions with tissue and organs as recited in claim 59. Thus, claim 59 patentably distinguishes over Mulhauser, such that the rejection under § 102 should be withdrawn.

Claims 60 and 62 depend from claim 59 and are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 47, 51, 52, 55, 57, 58, 61, 63, and 64 under 35 U.S.C. § 103(a) as being unpatentable over Mulhauser in view of Eldridge (U.S. 6,120,539). Applicants respectfully traverse these rejections.

Without acceding to the propriety of the combination as suggested by the Examiner, claims 47, 51, and 52 depend from claim 46 and are patentable for at least the same reasons set

forth above. Similarly, claims 55, 57, 58, 61, 63, and 64 depend from claim 53 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

#### Additional Claims

Claims 65-71 have been added to further define Applicants' invention.

Independent claim 65 is directed to a prosthetic repair fabric for repairing a tissue or muscle wall defect. The prosthetic repair fabric comprises a layer of mesh fabric that is susceptible to the formation of adhesions with sensitive tissue and organs. The layer of mesh fabric includes first and second sides, an edge extending between the first and second sides, a margin section proximate to the edge and an interior body section surrounded by the margin section. The prosthetic repair fabric also comprises at least one barrier layer that inhibits the formation of adhesions with sensitive tissue and organs. The barrier layer is disposed on at least a portion of the interior body section of the layer of mesh fabric to inhibit the formation of adhesions between the portion of the interior body section and adjacent sensitive tissue and organs. The prosthetic repair fabric further comprises an edge barrier that inhibits the formation of adhesions with sensitive tissue and organs. The edge barrier is adapted to isolate at least a portion of the edge of the mesh fabric from adjacent sensitive tissue and organs.

Claim 65 patentably distinguishes over the references of record which do not teach or suggest a barrier layer disposed on at least a portion of the interior body section of the layer of mesh fabric to inhibit the formation of adhesions between the portion of the interior body section and adjacent sensitive tissue and organs, and an edge barrier to isolate at least a portion of the edge of the mesh fabric from adjacent tissue and organs as recited in claim 65. As discussed above, nothing in Mulhauser indicates that the frame has any adhesion inhibiting characteristics. Mulhauser also does not teach or suggest a barrier layer that is disposed on an interior body section of the mesh fabric in combination with an edge barrier.

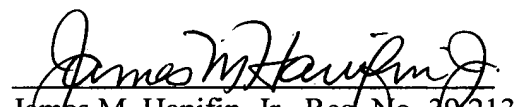
Claims 66-71 depend from claim 65 and are patentable for at least the same reasons.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

  
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